



[3510-16]

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No.: PTO-P-2015-0075]

Grant of Interim Extension of the Term of U.S. Patent No. 5,808,146; fluciclovine (¹⁸F)

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice of Interim Patent Term Extension.

SUMMARY: The United States Patent and Trademark Office has issued an order granting interim extension under 35 U.S.C. § 156(d)(5) for a one-year interim extension of the term of U.S. Patent No. 5,808,146.

FOR FURTHER INFORMATION CONTACT: Mary C. Till by telephone at (571) 272-7755; by mail marked to her attention and addressed to the Commissioner for Patents, Mail Stop Hatch-Waxman PTE, P.O. Box 1450, Alexandria, VA 22313-1450; by fax marked to her attention at (571) 273-7755; or by e-mail to Mary.Till@uspto.gov.

SUPPLEMENTARY INFORMATION: Section 156 of Title 35, United States Code, generally provides that the term of a patent may be extended for a period of up to five years if the patent claims a product, or a method of making or using a product, that has been subject to certain defined regulatory review, and that the patent may be extended for interim periods of up to one year if the regulatory review is anticipated to extend beyond the expiration date of the patent.

On October 22, 2015, Emory University, the patent owner of record, timely filed an application under 35 U.S.C. § 156(d)(5) for an interim extension of the term of U.S. Patent No. 5,808,146. The patent claims the active ingredient fluciclovine (^{18}F) of the drug product AxuminTM. The application for patent term extension indicates that New Drug Application (NDA) 208054 was submitted to the Food and Drug Administration (FDA) on September 28, 2015. In a letter dated October 8, 2015, FDA acknowledged receipt of NDA 208054 for “AxuminTM ([F-18] Fluciclovine)”.

Review of the patent term extension application indicates that, except for permission to market or use the product commercially, the subject patent would be eligible for an extension of the patent term under 35 U.S.C. § 156, and that the patent should be extended for one year as required by 35 U.S.C. § 156(d)(5)(B). Because the regulatory review period has continued beyond the original expiration date of the patent, November 9, 2015, interim extension of the patent term under 35 U.S.C. § 156(d)(5) is appropriate.

An interim extension under 35 U.S.C. § 156(d)(5) of the term of U.S. Patent No. 5,808,146 is granted for a period of one year from the original expiration date of the patent.

November 18, 2015

Date

Robert Bahr

Acting Deputy Commissioner for Patent Examination Policy

United States Patent and Trademark Office

[FR Doc. 2015-29887 Filed: 11/23/2015 8:45 am; Publication Date: 11/24/2015]